

REMARKS

The amendments to the specifications are fully supported by original specification and are made simply to correct typographical and/or clerical errors that inadvertently occurred at the time of filing. No new matter has been added by way of these specification amendments. Claims 4 and 7-15, are presently pending for the Examiner's review and consideration. No amendments have been made to the claims herein.

The Examiner has restricted the invention into seven (7) groups:

- I. Claims 4 and 15, drawn to a compound;
- II. Claims 7-9, drawn to a pharmaceutical composition;
- III. Claim 10, drawn to a first method of using said compound;
- IV. Claim 11, drawn to a second method of using said compound;
- V. Claim 12, drawn to a third method of using said compound;
- VI. Claim 13, drawn to a fourth method of using said compound; and
- VII. Claim 14, drawn to a fifth method of using said compound.

On February 24, 2003, Applicants' Attorney made a provisional election of Group I, with traverse, in response to the telephonic restriction request. Applicants' affirm the election of Group I, claims 4 and 15, but still emphatically traverse.

Applicants maintain that the restriction requirement is improper since the claimed invention relates to the compound as set forth in independent claim 4 and the alleged restriction groups are nothing more than different preferred uses and compositions of the claimed compound.

Section 809.03 of the MPEP explains that "there are a number of situations that arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the application to one would be proper, **but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the inventions otherwise divisible.**"

"The most common types of linking claims, which, if allowed, act to **prevent** restriction between inventions that can otherwise be shown to be divisible, are

(A) **genus claims linking species claims;**" (emphasis added).

In the present application, it is clear that all of the claims are dependent on independent compound claim 4 (the genus or "linking" claim), where all other claims are dependent and linked to compound claim 4.

In this type of situation, wherein a linking claim is present, the restriction requirement is dependent on the non-allowance of the linking claim. If the linking claim is later found to be patentable, the restriction requirement must be withdrawn and the

nonelected species dependent on the linking claim should be rejoined and examined (MPEP §§ 809.03-04). The election of a species is simply to assist the Examiner in conducting a prior art review of the claims, but such a restriction is not proper if a linking claim is found to be allowable (MPEP § 803).

This is the precise situation in the present application. Applicant has discovered the compound recited in claim 4, with preferred embodiments and uses of the compound as set forth in dependent claims 7-15. If the compound of claim 4 is found to be patentable, all dependent claims 7-15 must also be examined because they are linked through the generic claim 4. Furthermore, the Office Action even explicitly states on page 3, that claim 4 is the generic claim. Therefore, claim 4 is a generic genus claim that links all of the other dependent claims together and the restriction is improper and should be withdrawn.

There are additional reasons that the restriction requirement is improper and should be reconsidered and either modified or removed entirely. The search of claim 4 has already been conducted by the Examiner, so no additional significant burden exists in examining the remaining claims. Additionally, claim 4 is directed to a single compound, and as such, there cannot possibly be sub-species because the claim does not recite a traditional "group" of compounds that contains a species therein. Furthermore, simply adding conventional carriers or excipients has been found by the Federal Circuit to generally lack separate patentability from the active ingredient, so claims 7-8, for example, cannot possibly be separate inventions merely because they recite pharmaceutical compositions of the active ingredient of claim 4. For these additional reasons, the restriction is improper and should be reconsidered and withdrawn.

Claims 4 and 15 were rejected for anticipation under 35 U.S.C. § 102(b) over an article by Paris *et al.*, Tetrahedron Letters, 39, 7287-90 (1998) ("Paris") for the reason set forth on page 5 of the Office Action. Applicants traverse.

Paris relates to a general synthesis for the production of peptide aldehydes on a solid support using ozonolysis. Paris fails to disclose any specific peptide (see the bottom of the flow chart on page 7288) let alone the specific compound of claim 4. Without some disclosure of the compound of Claim 4, Paris cannot possibly anticipate the compound of claim 4. Applicants, therefore respectfully request that this rejection be withdrawn.

Claims 4 and 15 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,025,471 to Deghenghi *et al.* ("Deghenghi") for the reason set forth on page 5.¹ Applicants traverse.

Deghenghi also fails to disclose the compound of claim 4, in a generic or specific sense. The compounds disclosed in Deghenghi are all of the structural formula disclosed at col. 2, line 3:

A-B-D-Mrp-C-E

in which the abbreviation "D-Mrp" stands for the amino acid 2-alkyl-tryptophan (see col. 1, lines 54 and 55). All of the compounds in Deghenghi require and consist of D-Mrp.

In contrast, the compound of Claim 4 does not contain a D-Mrp group. In this respect, the compounds disclosed in Deghenghi can in no way destroy the novelty of Claim 4 of the present invention. Thus, Applicants respectfully request that this rejection be removed.

Claims 4 and 15 were rejected under 35 U.S.C. § 103(a), as being obvious over Paris or Deghenghi as noted above. Applicants again traverse.

As discussed above, Deghenghi and Paris each fail to disclose or suggest the specific compound of claim 4, even when taken in combination. Furthermore, neither reference provides motivation to one of ordinary skill in the art to make or isolate the compound of claim 4. In fact, Paris does not even teach specific peptides, as previously discussed. Further, Deghenghi relates only to peptides comprising the amino acid 2-alkyl-tryptophan (D-Mrp) and fails to provide any motivation or reasonable expectation of success to make a compound like that presently recited in claim 4, with no D-Mrp amino acid residue present. Therefore, Paris and Deghenghi, alone or in combination, fail to teach the compound of claim 4.

Furthermore, there is no motivation or suggestion in either reference to make or use the compound of claim 4 in pharmaceutical compositions or for methods of treatment. *In re Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir., 2002) (finding that the Board of Patent Appeals and Interferences improperly relied upon common knowledge and common sense of person of ordinary skill in art to find invention of patent application obvious over

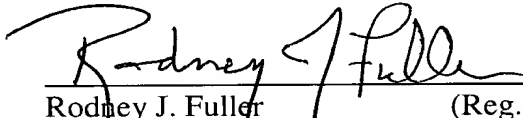
¹ Applicants note that there are three (3) Deghenghi *et al.* references of record in this application. The Examiner cited U.S. Patent No. 6,025,471 to Deghenghi *et al.* on the Form-892 attached to the Office Action, which is the only Deghenghi *et al.* cited by the Examiner. It is the Examiner's obligation to cite the best references at his or her command, and "the particular part relied upon must be designated as nearly as practicable. The pertinence of each reference . . . must be clearly explained. . . ." 37 C.F.R. § 1.104(c)(2).

combination of two prior art references, since factual question of motivation to select and combine references could not be resolved on subjective belief and unknown authority). In view of these facts, Applicants respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn, since no *prima facie* case of obviousness has been stated on the record.

Accordingly, Applicants believe that the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with the Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

Date 6/11/03


Rodney J. Fuller (Reg. No. 46,718)
For: Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN
Customer Number: 28765

(202) 371-5838